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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO
08/887,577	07/03/97	WANG	

EXAMINER

HM11/0829

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ART UNIT	PAPER NUMBER
PROPER	10

DATE MAILED: 08/20/98

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OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-22 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☒ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-22 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

1. ***Restriction Requirement:***

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A **dedicated** Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, PhD., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. **Please limit the use of this dedicated Fax number to responses to Written Restrictions.**

No attempt was made to call for an oral election from Ed Ching because Mr. Ching had informed the Examiner in previous calls regarding applications by the Assignee that oral elections would not be possible and that the restrictions should be issued in writing.

2. First of all it is pointed out that the claims have been presented in very poor format and constitute an improper Markush format for the various chemokine or chemokine receptor products, their fragments and fusion products, as well as the various method claims, because each of the products and the methods are clearly patentably distinct, wherein independent or separate claims should have been presented to each of these separate products and to the separate method. Many of the claims also list identifying characteristics **as well as** alternative embodiment/claim limitations (such as cl 3a-3e, 3j, 3m, 3n etc **as compared** to 3f-3g,3l, 3q, 3v etc) that really should not appear in this format. This format also causes the restriction and office actions to be extremely long because the Examiner has to constantly point out numerous defects in claim language, format, and claim limitations. Despite such the restriction will be set forth relative to these distinct product as best as possible, irrespective of whether these products or methods represent claim designation of 1a, 1b, 1c, 1d etc. Applicants patent counsel has been advised of this several time in other applications from the assignee, but has refused to comply. The Examiner has also have telephone conversation with the Patent Counsel to further point out the problems with such applications and the claims so that many of the problems that exist with the claims can be avoided with the filing of more appropriate claims in subsequent applications. The Examiner has also suggested more appropriate claim's language in other applications, but this can not be continuously done in the various office actions issued by the Examiner, as many of these defects are things that the Patent Counsel should not have made, and should correct, based on the constant urging of this Examiner, as well as other Examiners who handle applications filed by DNAX. If the Patent Counsel does not make a conscious effort to correct this format, exemplary applications will be forwarded to The Office of Enrollment and Discipline for their review, in view of the fact that the Patent Counsel has informed the Examiner that claims are filed in this manner as a cost-saving effort, and/or that multiple products are being filed together as a means of cost-saving so that the Assignee can later determine which products they actually want to pursue.

When the election is made, applicant's counsel is advised too **please** present amended claims that are only directed to a single product-if the election is to a product rather than a method. Applicants appear to have combined the concepts from three different provisional applications in which 5 different chemokines or chemokine receptors are being claimed-some where multiple specie forms are claimed. This, and the format in which the claims are written has made it difficult to reasonably separate these groups and has caused the claims to be directed to several inventive groups that will be shown to be patentably distinct.

Additionally, certain subpart of the claims are directed to a kit, it is not clear if the compositional make-up of the claims are intended to reflect a kit to the protein, antibody, nucleic acids or a combination of these products. Further, if applicant really intend to have claims to a proper kit and the claims are properly amended to reflect such (multiple elements and physical features to properly define a kit), then these claims to the distinct products may be restricted out from the recited product that they are presently grouped with.

ALL OF THIS IS BEING POINTED OUT AT THIS TIME SO THAT APPLICANTS CAN CORRECT THE VERY OBVIOUS ERRORS; SO AS TO ISSUE AN OFFICE ACTION ON THE MERITS OF WHAT IS INTENDED; AND SO AS TO REDUCE THE TIME FOR COMPLIANCE AND TO ADVANCE PROSECUTION.

Applicant must elect **only one of the single products or single methods** which use only one of the single products as set forth in the 48 Groups.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

In brief, 1) claims 1-3 are directed to multiple chemokine or chemokine receptor products and possible compositions and/or kits; 2) claims 4-5, 6, 7-13 are directed to nucleic acid, vectors, and host cells encoding the various multiple chemokine or chemokine receptor products; 3) claims 14-16 are directed to binding compound or antibodies and hybridoma directed to multiple chemokine or chemokine receptor products; 4) claim 17 is directed to methods of purifying any one of multiple chemokine or chemokine receptor products; 5) claim 18 is directed to methods of making complexes comprising any one of the multiple chemokine or chemokine receptor products; 6) claims 19(I) and 20-22 are directed to methods of using any one of the multiple chemokine or chemokine receptor products or their mutein; 7) claims 19(I) and 20-22 are directed to methods of using agonist to any one of the multiple chemokine or chemokine receptor products; and finally, 8) claims 19(ii) and 20-22 are directed to using antibody antagonist to any one of the multiple chemokine or chemokine receptor products. It is also pointed out that in view of the format of the claims, and in the interest of not having to set forth so many more groups, if applicants are interested in the examination of such things as the fusion protein, conjugates or immunogenic peptides (subparts of claim 3) to any one of the 6 products, then they should expressly elect such, since these are clearly considered to be patentably distinct products from the protein/polypeptides per se.

1. Claims 1(I) and portions of 2-3, drawn to mouse Teck proteins, fragments polypeptides and kits/composition.
2. Claims 1(I) and portions of 2-3, drawn to human Teck, fragments, polypeptides and kits/compositions.
3. Claims 1(ii) and portions of 2-3, drawn to human MIP-3α proteins, fragments polypeptides and kits/composition.
4. Claims 1(iii) and portions of 2-3 drawn to human MIP-3β proteins, fragments polypeptides and kits/composition.
5. Claims 1(iv) and portions of 2-3 drawn to human DC CR proteins, fragments polypeptides and kits/composition.
6. Claims 1(v) and portions of 2-3, drawn to human M/DC CR proteins, fragments polypeptides and kits/composition.

The inventions of Groups 1-6 are classified in classes 530 and 424, subclasses 351 and 85.1 respectively.

7. Claims 4-13, drawn to DNA encoding mouse Teck proteins, fragments polypeptides, vectors, host cells and method of making.
8.. Claims 4-13, drawn to DNA encoding human Teck, fragments, polypeptides vectors, host cells and method of making.
9. Claims 4-13, drawn to DNA encoding human MIP-3α, proteins, fragments polypeptides, vectors, host cells and method of making.
10. Claims 4-13, drawn to DNA encoding human MIP-3β proteins, fragments polypeptides, vectors, host cells and method of making.
11. Claims 4-13, drawn to DNA encoding human DC CR proteins, fragments polypeptides, vectors, host cells and method of making.
12. Claims 4-13, drawn to DNA encoding human M/DC CR proteins, fragments polypeptides, vectors, host cells and method of making

The inventions of Groups 7-12 are classified in classes 536 and 435, subclasses 23.5 and 69.5 respectively.

13. Claims 14-16, drawn to antibodies or antigen binding portions to mouse Teck and kits/composition.
14. Claims 14-16, drawn to antibodies or antigen binding portions to human Teck and kits/compositions.
15. Claims 14-16, drawn to antibodies or antigen binding portions to human MIP-3α, and kits/composition.
16. Claims 14-16, drawn to antibodies or antigen binding portions to human MIP-3β and kits/composition.
17. Claims 14-16, drawn to antibodies to human DC CR and kits/composition.
18. Claims 14-16, drawn to antibodies to human M/DC CR and kits/composition.

The inventions of Groups 13-18 are classified in classes 530 and 424, subclasses 388.23+ and

145.1 respectively.

19. Claim 17, drawn to methods of purifying the mouse Teck
20. Claim 17, drawn to methods of purifying the human Teck
21. Claim 17, drawn to methods of purifying human MIP-3α
22. Claim 17, drawn to methods of purifying the human MIP-3β
23. Claim 17, drawn to methods of purifying the human DC CR
24. Claim 17, drawn to methods of purifying the human M/DC CR .

The inventions of Groups 19-24 are classified in class 530 subclasses 351 and 412+ respectively.

25. Claim 18, drawn to methods of making complexes with mouse Teck
26. Claim 18, drawn to methods of making complexes with human Teck
27. Claim 18, drawn to methods of making complexes with human MIP-3α
28. Claim 18, drawn to methods of making complexes with human MIP-3β
29. Claim 18, drawn to methods of making complexes with human DC CR
30. Claim 18, drawn to methods of making complexes with human M/DC CR .

The inventions of Groups 25-30 are classified in classes 530 and 424, subclasses 351+ and 85.1+ respectively.

31. Claims 19-22, drawn to method of using agonist to mouse Teck
32. Claims 19-22, drawn to method of using agonist to human Teck
33. Claims 19-22, drawn to method of using agonist to human MIP-3α
34. Claims 19-22, drawn to method of using agonist to human MIP-3β
35. Claims 19-22, drawn to method of using agonist to human DC CR
36. Claims 19-22, drawn to method of using agonist to human M/DC CR

The inventions of Groups 31-36 are classified in classes and subclasses vary depending on the nature and make-up of the agonist and the method of modulation.

37. Claims 19-22, drawn to method of using antagonist antibodies to mouse Teck
38. Claims 19-22, drawn to method of using antagonist antibodies to human Teck
39. Claims 19-22, drawn to method of using antagonist antibodies to human MIP-3α
40. Claims 19-22, drawn to method of using antagonist antibodies to human MIP-3β
41. Claims 19-22, drawn to method of using antagonist antibodies to human DC CR
42. Claims 19-22, drawn to method of using antagonist antibodies to human M/DC

CR
The inventions of Groups 37-42 are classified in classes and subclasses varies depending on the nature and make-up of the antagonist and the method of modulation.

43. Claims 19-22, drawn to method of using mouse Teck protein, peptide or mutein.

44. Claims 19-22, drawn to method of using human Teck protein peptide or mutein.

45. Claims 19-22, drawn to method of using human MIP-3α protein peptide or mutein.

46. Claims 19-22, drawn to method of using human MIP-3β protein peptide or mutein.

47. Claims 19-22, drawn to method of using human DC CR protein peptide or mutein.

48. Claims 19-22, , drawn to method of using human M/DC CR protein peptide or mutein.

The inventions of Groups 43-48 are classified in classes 435, subclasses 7.1+

The inventions are distinct, each from the other because:

Inventions Groups I-6, compared to Groups 7-12 or Groups 19-24 respectively are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the individual protein can be made by a materially different process, such as their isolation from nature, other than with the aid of immunoaffinity chromatography or they could be prepared by chemical synthesis. Furthermore, the DNA can be used other than to make the encoded protein, such as its use as probe or in other diagnostics, or to make transgenic animal or in therapy.

Inventions Groups 13-18, compared to Groups 19-24 or Groups 25-30, respectively are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in

a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies, as claimed, can be used in materially different process, such as their use in various therapeutic methods, or they can be used in other diagnostic methods.

Inventions of Groups 6-10 as compared to Groups 46-50 respectively are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the fusion protein can be used therapeutically or they can be used in other diagnostic methods.

Inventions of Groups 11-15 as compared to Groups 31-35 respectively are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies, as claimed, can be used in materially different methods such as their use therapeutically or in other diagnostic methods.

Inventions of Group 1-6 as compared to Groups 43-48, respectively are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein can be used in materially different methods, such as their use to make antibodies or other modified form or they could be used in various diagnostic methods, or they could be used as probes.

It is further pointed out that although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for multiple/different products, restriction is deemed to be proper because the products appear to constitute patentably distinct inventions. The inventive products of Groups 1-18 are directed to products that are structurally, physically

and functionally distinct and if determined to be patentable they would also be patentably distinct, and in fact, each of the protein products of Groups 1-6 are clearly distinct protei products. Furthermore, these products are not required one for the other, nor are they required for each of the various methods of Groups 25-48.

In a similar manner it is further pointed out that although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for multiple/different methods, restriction is deemed to be proper because the methods appear to constitute patentably distinct inventions. The inventive methods of Groups 25-48 require the use of different steps/methods; elements/agents that are physically and functionally distinct; there are different starting elements and the final outcome/results are different for these different methods that cover various diagnostics and therapeutic methods; and if determined to be patentable they would also be patentably distinct. In fact the different methods which use the 6 distinct product are all distinct. Furthermore, these methods are not required one for the other, or does each method require the use of each of the products of Groups 1-18.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications which are not co-extensive. And there are different issues for the search and examination of each group, which would be an **extremely unduly burden**, accordingly, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Advisory Information:

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to **Garnette D. Draper, Art Unit 1646, whose telephone number is (703) 308-4232.** Examiner Draper can normally be reached Monday through Friday, 9:30 A.M. to 6:00 P.M.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.

GARNETTE D. DRAPER
PRIMARY EXAMINER
GROUP 1800